

14. THERMOMETER (DATA LOGGER) POLICY

Montana VFC Thermometer Requirements

The CDC and the Montana Immunization Program require thermometers in all VFC vaccine storage units that meet the following requirements:

Requirement

- Are certified calibrated/tested as accurate against NIST or ASTM measurement standards annually or within the timeframe recommended by the manufacturer evidenced by a current Certificate of Traceability and Calibration Testing, Report of Calibration Testing, or Instrument Calibration Report.
- Have alarms for out-of-range temperatures
- Display current, minimum, and maximum temperatures
- Have a low battery indicator
- Are accurate to +/- 1°F (0.5°C)
- Have a memory that stores at least 4,000 readings
- Use a thermocouple probe in a buffered medium such as glycol, glass beads, or aluminum block

State-Supplied Thermometers – Data Loggers

The Montana Immunization Program provides program-compliant digital Data Loggers to all VFC providers in Montana. Data Loggers are electronic thermometers that continuously record and store temperature data and indicate through a warning light when out-of-range temperatures have been encountered. Data Loggers interface with a computer so that data can be removed, reviewed, and saved.

Immunization Program Responsibilities

- The Immunization Program supplies Data Loggers for all public vaccine storage units and one backup free-of-charge to VFC providers in Montana. Each Data Logger comes with:
 - Instrument Calibration Report
 - Data logger cradle and attachment kit for mounting on outside of storage unit
 - Thermocouple probe housed in a glycol-containing bottle and connected to the Data Logger by a 10-foot wire. Acrylic stand for the glycol bottle
 - Extra battery
 - Free EasyLog® Software
 - Montana specific *Data Logger Instruction Manual*
- If a provider chooses to supply their own program-compliant thermometers, they must meet the requirements as defined above. The Immunization Program must approve provider-supplied thermometers and issue a memo exempting the provider from using a State-supplied Data Logger. To obtain thermometer approval, providers must submit to the Immunization Program:
 - One week of temperature recordings for each public vaccine storage unit
 - Thermometer product specifications

Requirement

- Current Certificate of Traceability and Calibration Testing, Report of Calibration Testing, or Instrument Calibration Report that meets CDC requirements.
- Institutional policies on thermometer calibration, manual checking of temperatures twice daily, and out of range temperature response.
- The Montana Immunization Program provides training, technical support, and written instructions for using the Data Loggers.
- The Montana Immunization Program provides technical assistance to VFC providers in responding to temperature excursions.
- The Montana Immunization Program facilitates a recalibration program for State-supplied Data Loggers at the provider's expense (terms of recalibration may change year to year).
- As a quality control measure, the Immunization Program randomly requests temperature-monitoring information from providers.
- The Immunization Program reviews Data Logger data and approves storage units/thermometers for:
 - New VFC providers
 - Providers setting up a new VFC storage unit
 - Providers reinstating a VFC storage unit after a repair
 - Providers commissioning a new Data Logger or other program-compliant thermometer.

Provider Responsibilities – Listed below are the requirements of the Immunization Program Data Logger Program:

Requirement

- All VFC providers must use a State-supplied Data Loggers in each VFC vaccine storage unit unless they have an Immunization Program-approved thermometer that meets the VFC requirements as defined in this section.
- If using State-supplied Data Loggers, providers must have a Windows®-based computer for running the Data Logger software and a storage location for the Data Logger data.
- VFC providers must have all VFC vaccine storage units/thermometers approved for use by following the instructions on page 47 (*Storage Unit Approval*).
- Providers are responsible for Data Logger re-calibration and may use the state-facilitated re-calibration program or a vendor of their choice as long as they offer CDC-compliant calibrations.
- Providers must keep the State-supplied backup thermometer in a well-communicated location ready-to-use if needed.
- Retain paper temperature logs, trouble-shooting logs, and data logger data for three years.
- Providers terminated from the VFC Program must return State-supplied Data Loggers to the Immunization Program.

In the routine use of Data Loggers, providers must:

- Prior to first use and after each data download, use the provided software to set up and activate each Data Logger according to Immunization Program guidance.
- After activation, properly install the Data Logger in each VFC vaccine storage unit.
- Manually perform the daily temperature monitoring activities outlined in Section 13, (page 48 – *Routine Temperature Monitoring*) using the state-supplied data logger or other program-complaint thermometer.

- Respond to out-of-range temperature indications as outline in Section 13, (page 49 – *Out of Range Temperatures*).
- At the end of every month (prior to reconciling inventory and ordering vaccine) download, review, and save Data Logger data for the previous month. Save monthly Data Logger data and paper temperature logs for three years.

See the *Montana VFC Data Logger Instruction Manual* for specific details on setting up and using your Data Logger. A copy is available on our website at www.immunization.mt.gov under the “VFC” link.